Prevaccination Checklist for COVID-19 Vaccines

SUBVICES (R. CODC)

Information for Healthcare Professionals

Using the prevaccination checklist completed by the recipient, review clinical guidance based on the answers to the questions to determine if COVID-19 vaccine can be given. Use this guidance with:

and Older

- Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States
- Advisory Committee on Immunization Practices on Immunization General Best Practice Guidelines

Vaccine Administration:

COVID-19 vaccines are administered by IM injection and can be given at the same clinical visit as other routinely administered vaccines using separate needles, syringes and injection sites. Exception: Orthopoxvirus vaccines (mpox) have additional considerations. <u>See section 8 of this guidance</u>. Other routine vaccines can also be administered any time before or after COVID-19 vaccination.

Syncope (fainting) might occur in association with any injectable vaccine, especially in adolescents. Consider observing vaccine

1. How old is the person to be vaccinated?

 COVID-19 Vaccination Clinical & Professional Resources for each vaccine product

Interim COVID-19 Immunization Schedule for Ages 6 Months

recipients, vaccination providers, particularly when vaccinating adolescents, for 15 minutes after vaccination.

Additionally, providers should consider observing some people with a history of allergic reactions for 30 minutes after COVID-19 vaccination. <u>See Sections 6 and 7</u> in this guidance and <u>Management of Anaphylaxis at COVID-19 Vaccination Sites | CDC</u> for guidance.

Clinical considerations based on the age of the recipient include:

COVID-19 vaccines products (monovalent and bivalent) have different age indications.

- Janssen COVID-19 Vaccine (monovalent) can be administered to persons 18 years of age and older in certain limited situations due to safety considerations.
- Novavax COVID-19 Vaccine (monovalent) can be administrated to persons 12 years of age and older.
- Moderna COVID-19 Vaccine (monovalent, bivalent) can be administered to persons ages 6 months of age and older.
- Pfizer-BioNTech COVID-19 Vaccine (monovalent, bivalent) can be administered to persons 6 months of age and older.

Use the <u>manufacturers' fact sheets for healthcare professionals</u> and <u>CDC clinical materials for healthcare professionals</u> and to identify the correct product based on the vaccine composition and recipient's age.

People receiving mRNA or Novavax COVID-19 vaccines, especially males ages 12–39 years, should be made aware of the rare risk of myocarditis and/or pericarditis following receipt of these COVID-19 vaccines and the benefit of COVID-19 vaccination in reducing the risk of severe outcomes from COVID-19, including the possibility of cardiac sequelae. Counseling should include the need to seek care if symptoms of myocarditis or pericarditis, such as chest pain, shortness of breath, or tachycardia develop after vaccination, particularly in the week after vaccination. Extending the interval between these vaccines dose to 8 weeks might reduce the risk.

Note: There are some persons the extended interval should not be considered including those who are:

- Moderately or severely immunocompromised
- Adults ages 65 years and older;
- In situations in which there is increased concern about COVID-19 community levels or an individual's higher risk of severe disease.

Additional recipient education materials

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2. Is the person to be vaccinated sick today?

People with mild illnesses can be vaccinated. Do not withhold vaccination if a person is taking antibiotics.

While there is no evidence acute illness reduces vaccine efficacy or increases adverse reactions, as a precaution, **delay vaccinating patients with moderate or severe illness** until the illness has improved.

Defer vaccination of people with current SARS-CoV-2 infection. For those with

- Symptoms: defer vaccination until recovery from the acute illness and isolation has been discontinued.
- Asymptomatic infection: defer vaccination until isolation has been discontinued.

This recommendation applies regardless of whether the SARS-CoV-2 infection occurred before the recipient received an initial dose or between doses. Viral or serological testing to assess for current or prior infection solely for the purpose of vaccinedecision making is not recommended.

3. Has the person to be vaccinated ever received a dose of COVID-19 vaccine?

COVID-19 vaccination is recommended for everyone 6 months of age and older. For the primary series, Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines are recommended. The same vaccine product should be used for all primary series doses.

Moderna and Pfizer-BioNTech are recommended for booster doses. A bivalent booster dose of COVID-19 vaccine is recommended for persons 6 months of age and older with the exception of children ages 6 months through 4 years who completed a primary series of Pfizer-BioNTech COVID-19 Vaccine; regardless of which Pfizer-BioNTech vaccine (i.e., monovalent or bivalent) was administered for the third primary series dose.

A monovalent Novavax booster dose (instead of a bivalent mRNA booster dose) may be used in limited situations for persons ages 18 years and older who completed any

monovalent primary series, and have not received **ANY** previous booster dose(s), and are unable (i.e., contraindicated or not available) or unwilling to receive an mRNA vaccine and would otherwise not receive a booster dose.

Janssen COVID-19 Vaccine can be administered to persons 18 years of age and older in certain limited situations due to safety considerations.

To determine previously administered COVID-19 doses, check medical records, immunization information systems, and vaccination record cards. If the vaccine product previously administered cannot be determined, is no longer available, or contraindicated, any age-appropriate COVID-19 vaccine product may be administered at least 28 days after the first dose.

<u>Use the Interim Immunization Schedule for Ages 6 Months</u> and Older to schedule doses

Persons who received COVID-19 vaccine outside the United States

Vaccination guidance for people vaccinated outside of the United States can be found in the link <u>Interim Clinical Considerations for</u> <u>Use of COVID-19 Vaccines: Appendices, References, and Previous Updates | CDC</u>

4. Does the recipient have a health condition or undergoing treatment that makes them moderately or severely immunocompromised?

People with moderate or severe immunocompromising conditions or people who take immunosuppressive medications or therapies are at increased risk for severe COVID-19 disease. COVID-19 vaccines may be administered to people with underlying medical conditions, such as HIV infection or other immunocompromising conditions, or who take immunosuppressive medications or therapies, and who have no contraindications to vaccination. People can self-report if they are moderately or severely immunocompromised. Vaccinators should not deny COVID-19 vaccination to a person due to lack of documentation of immune status.

<u>Use the Interim Immunization Schedule for Ages 6 Months</u> and Older to schedule doses

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5. Has the person to be vaccinated received a hematopoietic cell transplant (HCT) or CAR-T-cell therapy since receiving COVID-19 vaccine?

HCT and CAR-T-cell recipients who received doses of COVID-19 vaccine prior to or during HCT or CAR-T cell therapy, should be revaccinated for any monovalent primary series and bivalent booster doses received before or during treatment at least 3 months (12 weeks) after transplant or CAR-T-cell therapy. After revaccination with the primary series, the patient should receive 1 bivalent booster dose. There is no revaccination for monovalent booster doses. Additional information can be found at: Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States

6. Has the person to be vaccinated ever had an allergic reaction to:

- A previous dose OR a component of any COVID-19 vaccine
- A previous dose of COVID-19 vaccine?

People with a severe allergic reaction^{*} to a previous COVID-19 vaccine dose or a known (diagnosed) allergy to a component of the vaccine have a contrainidcation to the same type of COVID-19 vaccine (mRNA, Novavax, Janssen).

People who had an immediate (less than 4 hours), but nonsevere allergic reaction to a previous dose of COVID-19 vaccine, have a precaution to receiving the same type of COVID-19 vaccine product. Although they can receive the same product, a different COVID-19 vaccine product can also be administered. **Providers should consider observing these patients for 30 minutes after vaccination**

People with a contraindication to one type of COVID-19 vaccine (e.g., mRNA) should not receive any doses of that type of vaccine and have a precaution to the other types of vaccine[†].

For COVID-19 vaccine components see the vaccine product's package insert or healthcare provider facts sheet: www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

Potential characteristics of allergic reactions, vasovagal reactions, and vaccine side effects following COVID-19 vaccination

In patients who experience post-vaccination symptoms, determining the etiology (including allergic reaction, vasovagal reaction, or vaccine side effects) is important to determine whether a person can receive additional doses of the vaccine. Additional information can be found at <u>Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination</u>.

7. Has the person to be vaccinated ever had anaphylaxis after another vaccine (other than COVID-19 vaccine) or another injectable medication?

A history of anaphylaxis to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of COVID-19 vaccines) is a precaution to COVID-19 vaccines. This also applies if the non-COVID-19 vaccine or therapy has multiple components, one or more of which is a component of a COVID-19 vaccine, and it is unknown which component elicited the allergic reaction. Vaccine may be given, but counsel patients about unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination. Deferral of vaccination and/or consultation with an allergist-immunologist should be considered. **Providers should consider observing these patients for 30 minutes after vaccination.**

^{*} When vaccine recipients report a history of an immediate allergic reaction, providers should attempt to determine whether reactions reported following vaccination are consistent with immediate allergic reactions versus other types of reactions commonly observed following vaccination, such as vasovagal reaction or postvaccination side effects (which are not contraindications to receiving additional doses of that vaccine).

⁺ People with a known allergy to polysorbate have a contraindication to both Novavax and Janssen COVID-19 vaccines and a precaution to mRNA COVID-19 vaccines. In all other cases, an allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the other types.

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8. Clinical Considerations:

Response	Consideration
History of myocarditis or pericarditis	 Development of myocarditis or pericarditis after a dose of an mRNA (Moderna, Pfizer-BioNTech) or Novavax COVID-19 vaccine is a precaution to a subsequent dose of any COVID-19 vaccine and subsequent doses should generally be avoided.
	 If after a risk assessment, the decision is made to receive a subsequent COVID-19 vaccine dose, the person should wait until after their episode has resolved. Considerations for subsequent COVID-19 vaccination may include:
	 The myocarditis or pericarditis was considered unrelated to vaccination with Moderna, Novavax, or Pfizer-BioNTech (e.g., due to SARS-CoV-2 or other viruses), especially if the myocarditis or pericarditis diagnosis occurred more than 3 weeks after the most recent dose of COVID-19 vaccine
	 Personal risk of severe acute COVID-19 (e.g., age, underlying conditions)
	 Timing of any immunomodulatory therapies; Consult <u>ACIP's General Best Practice Guidelines for Immunization</u>
	For information on potential use of Janssen COVID-19 Vaccine in this situation, see <u>Appendix A</u>
	 Persons who have a history of myocarditis or pericarditis unrelated to mRNA (Moderna, Pfizer-Bio- NTech) or Novavax COVID-19 vaccination may receive any currently FDA-approved or -authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has resolved.
History of multisystem inflammatory syndrome; either MIS-C (children) or MIS-A (adults)	 Persons with a history of multisystem inflammatory syndrome; either MIS-C (children) or MIS-A (adults) is a precaution to receipt of COVID-19 vaccine.
	Considerations when conducting a risk assessment for potential COVID-19 vaccination
	Healthcare providers and health departments may also request a consultation from the <u>Clinical</u> <u>Immunization Safety Assessment Project</u>
History of an immune- mediated syndrome characterized by thrombosis and thrombocytopenia, such as heparin-induced thrombocytopenia (HIT)	 Janssen COVID-19 vaccine is not recommended for persons with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as spontaneous or classic HIT.
	These persons should receive an mRNA (ie. Moderna or Pfizer-BioNTech) or Novavax COVID-19 vaccine.
History of thrombosis with thrombocytopenia syndrome (TTS)	 Janssen COVID-19 vaccine is contraindicated for persons with a history of TTS following a dose of Janssen COVID-19 vaccine (or other COVID-19 vaccines not currently authorized in the U.S. that are based on adenovirus vectors, e.g., AstraZenca).
	These persons should receive a booster dose of bivalent mRNA vaccine (Moderna, Pfizer-BioNTech). For additional guidance see Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendix A
History of Guillain- Barré Syndrome (GBS)	 A history of GBS, either before or after COVID-19 vaccination, is a precaution for receipt of Janssen COVID-19 Vaccine. An mRNA or Novavax COVID-19 vaccine is recommended.
	Persons who develop GBS within 6 weeks of Janssen COVID-19 vaccination should only receive an mRNA COVID-19 vaccine.

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Response	Consideration
History of prior COVID-19 disease in the last 3 months	 COVID-19 vaccination is recommended for everyone ages 6 months and older, regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection. People who recently had COVID-19 disease or SARS-CoV-2 infection (within the last 3 months) may consider delaying their primary series or booster dose dose by 3 months from symptom onset or positive test (if infection was asymptomatic). Individual factors such as risk of severe disease, COVID-19 community level, or characteristics of the predominant SARS-CoV-2 strain should be considered when determining whether to delay getting a booster dose after infection. NOTE: Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection is NOT RECOMMENDED for the purpose of vaccine decision-making.
Been vaccinated with mpox vaccine in the last 4 weeks?	 If an <u>orthopoxvirus vaccine</u> is recommended for prophylaxis in the setting of an orthopoxvirus (e.g., mpox) outbreak, orthopoxvirus vaccination should not be delayed because of recent receipt of a Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccine; no minimum interval between COVID-19 vaccination with these vaccines and orthopoxvirus vaccination is necessary. People, particularly adolescent or young adult males, might consider waiting 4 weeks after orthopoxvirus vaccination (either JYNNEOS or ACAM2000) before receiving a Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccine because of the observed risk for myocarditis and pericarditis after receipt of ACAM2000 orthopoxvirus vaccine and mRNA (i.e., Moderna or Pfizer-BioNTech) and Novavax COVID-19 vaccines and the unknown risk for myocarditis and pericarditis after JYNNEOS.